

## **REMARKS/ARGUMENTS**

The Office Action mailed January 25, 2006 has been reviewed and carefully considered. Claims 1-2, 6-25, 27-33, and 37-43 are pending in this application, with claims 1, 25, 32, and 43 being the only independent claims. Reconsideration of the above-identified application, as herein amended and in view of the following remarks, is respectfully requested.

### **Claim Amendments**

Claims 3-4, 26, and 34-35 are canceled without prejudice or disclaimer.

Independent claim 1 is amended to recite:

“wherein one of said shield and said barrel defines a track arrangement having an entry track and a lock-out track, said entry track and said lock-out track being joined at an intersection, and the other of said shield and said barrel includes a pin guidable in said track arrangement, said shield being movable by interaction with a patient’s skin from said first position to a second position against the urgency of said urging member when said needle cannula is inserted into a patient for delivery of the medicament, said pin moving along said entry track at least to the intersection and into said lock-out track during movement of said shield from the first position to the second position, and said shield being moveable from said second position to a third position by the urgency of said urging member upon removal of said needle cannula from said patient, wherein said forward tip of said needle cannula is covered by said shield when said shield is in said third position, said pin moving in said lock-out track during movement of said shield from said second position to said third position”.

Support for this amendment is found in original claim 3 and paragraph 0022 of the specification.

Independent claims 25, 32, and 43 are amended to include features similar to the above features of amended independent claim 1.

Dependent claims 5, 6, 9, 13, 16, 20, 23, 24, 36, 37, 39, and 42 are amended to be consistent with the above amendments to the independent claims.

### **Information Disclosure Statement**

The Office Action states that the Larsen reference in the IDS dated April 4, 2005 has not been considered because the document number has been incorrectly provided. The document number listed is 2002/004648 A1 which corresponds to the publication of an application in the name of Larsen. During a phone call, Examiner Han explained that listing of US published applications require seven digits after the slash. An IDS is submitted herewith listing Larsen in the proper format as 2002/0004648.

### **Rejection of claims under 35 U.S.C. §§102 and 103**

Claims 1-23 and 25-43 stand rejected under 35 U.S.C. §102 as anticipated by U.S. Patent No. 5,429,612 (Berthier).

Claim 24 stands rejected under 35 U.S.C. §103 as unpatentable over Berthier.

The present invention is directed to a safety syringe. It is desirable that safety syringes protect a user of the syringe from exposure to a contaminated cannula tip after use of the syringe. Measures for affording such protection include, for example, an automatically deployable shield which does not require significant, or any, manipulation by the user, and which shields the needle cannula tip from the user after use of the syringe.

Independent claim 1 recites “wherein one of said shield and said barrel defines a track arrangement having an entry track and a lock-out track, said entry track and said lock-out track being joined at an intersection, and the other of said shield and said barrel includes a pin guidable in said track arrangement”, “said shield being movable by interaction with a patient’s skin from said first position to a second position against the urgency of said urging member when said needle cannula is inserted into a patient for delivery of the medicament, said pin moving along said entry track at least to the intersection and into said lock-out track during

movement of said shield from the first position to the second position”, and “said shield being moveable from said second position to a third position by the urgency of said urging member upon removal of said needle cannula from said patient”.

Berthier fails to teach or suggest the above limitations. Berthier discloses a syringe having a cylindrical slideway 7 and a needle protector 8 arranged over the slideway 7. In the embodiment of Fig. 2, the slideway 7 has a track arrangement having a U-shaped groove 22 with two branches 23, 24 connected by a circumferential groove 25 (see col. 4, lines 35-39 of Berthier). The needle protector 8 has a resilient tongue 26 that enters the track arrangement. Berthier discloses that the resilient tongue 26 moves in branch 23 when the protector 8 moves in the uncovering direction (col. 4, lines 40-43). To move the resilient tongue 26 to the recess 29 at the termination of the branch 24, the protector 8 is pushed toward the circumferential portion 25 and rotated to place the tongue 26 in the branch 24 (col. 4, lines 53-58). Although manual rotation is not explicitly stated in Berthier, this is presumed, especially because the portion 25 connecting two branches 23, 24 of the U-shaped groove extends in a circumferential direction. This requirement for manual rotation increases the likelihood of a user of the device inadvertently coming into contact with an exposed, and possible contaminated, tip of the needle, especially because both of the user’s hands will be used to rotate the protector 8. Since the branches 23, 24 of Berthier do not intersect, Berthier fails to teach “said entry track and said lock-out track being joined at an intersection”, as expressly recited in independent claim 1.

Berthier also fails to teach or suggest “said shield being movable by interaction with a patient’s skin from said first position to a second position against the urgency of said urging member when said needle cannula is inserted into a patient for delivery of the medicament, said pin moving in said entry track at least to said intersection and into said lock-out track when the shield

moves from the first position to the second position”. In contrast, the tongue 26 of Berthier is not moved into the second branch 24 (e.g., a “lock-out track”) when the protector 8 is pushed back by the patient’s skin. Rather, the tongue only moves along branch 23 to the intersection of the branch 23 and the circumferential groove 25. The spring of Berthier is not able to move the protector 8 toward the covered position until the protector 8 is (manually) rotated to place the tongue 26 in branch 24. Since the tongue 26 of Berthier does not move into branch 24 by interaction with a patients skin, Berthier also fails to disclose teach or suggest “said shield being movable by interaction with a patient’s skin from said first position to a second position against the urgency of said urging member when said needle cannula is inserted into a patient for delivery of the medicament, said pin moving in said entry track at least to said intersection and into said lock-out track when the shield moves from the first position to the second position” and “said shield being moveable from said second position to a third position by the urgency of said urging member upon removal of said needle cannula from said patient”, as expressly recited in independent claim 1

In view of the above amendments and remarks, applicants respectfully submit that independent claim 1 is not anticipated by or unpatentable in view of Berthier.

Independent claims 25, 32, and 43 include similar limitations to independent claim 1 and are allowable for at least the same reasons as is independent claim 1.

Dependent claims 2, 5-24, 27-31, 33 and 36-42, each being dependent on one of independent claims 1, 25, and 32, are deemed to be allowable for at least the same reasons expressed above with respect to independent claims 1, 25 and 32, as well as for the additional recitations contained therein.

Dependent claims 16 and 42 recite “said lock-out track has two ends, said entry track intersecting said lock-out track at a location between said two ends of said lock-out track”.

Berthier fails to disclose this limitation because Berthier fails to disclose an entry track that intersects a lock-out track. Furthermore, the branches 23 and 24 are connected at their ends by a groove 25. Even if the branches are considered tracks, there are no intersections between two ends of any of the tracks. Accordingly, dependent claims 16 and 42 should be allowable for at least the additional reasons.

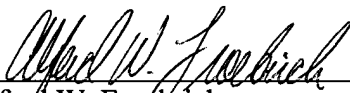
In view of the above amendments and remarks, the application is now deemed to be in condition for allowance and notice to that effect is earnestly solicited.

It is believed that no fees or charges are required at this time in connection with the present application. However, if any fees or charges are required at this time, they may be charged to our Patent and Trademark Office Deposit Account No. 03-2412.

Respectfully submitted,

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